

**DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN  
USED ACCORDING TO DIRECTIONS**

**4201. Misbranding of La Parfaite syringe. U. S. v. 161 Devices, etc. (F. D. C. No. 33280. Sample No. 1159-L.)**

**LIBEL FILED:** On or about June 12, 1952, Southern District of Florida.

**ALLEGED SHIPMENT:** On or about November 16, 1950, from Paris, France.

**PRODUCT:** 161 *La Parfaite syringes* in individual boxes at Highland City, Fla., together with a number of circulars entitled "Feminine Hygiene is made 100% Effective."

The device consisted of a porcelain fitting equipped with a rubber inlet tube and a rubber outlet tube. The rubber inlet tube had a number of openings near the tip and one opening at the very tip end. In operation, a supply of fluid under hydrostatic pressure would be forced into the vagina through the rubber inlet tube.

**RESULTS OF INVESTIGATION:** Upon receipt of the devices from France, the consignee, Mrs. Grace Kern, doing business as the Florida Hygienic Co., at Highland City, Fla., repackaged the devices into individual boxes, together with 1 copy of the above-mentioned circular which had been printed for the consignee.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the above-mentioned circular were false and misleading. The statements represented and suggested that use of the device was effective for insuring a sound, healthy body for women, enabling the penetration of a cleansing solution to all parts of the vaginal tract, preventing cancer which might be caused by bruising the uterus through use of other types of douching devices, and providing a safe method of douching. The device was not effective for the intended purposes, and it was not capable of fulfilling the promises of benefit made for it.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling since the jet of fluid emerging from the hole in the tip of the device would enter the uterus and cause injury.

The device was misbranded in the above respects while held for sale after shipment in interstate commerce.

**DISPOSITION:** November 16, 1953. Grace Kern, claimant, having filed an answer to the libel and later having withdrawn such answer, judgment of condemnation was entered and the court ordered that the devices and the labeling be destroyed.

**VIOLATIVE SALES OF PRESCRIPTION DRUGS**

**4202. Misbranding of pulvules containing a mixture of Seconal Sodium and Amytal Sodium. U. S. v. Arnold's Pharmacy, Inc., Richard Leipert, and Max Rosenthal. Motion denied to dismiss information and to suppress evidence. Plea of guilty. Fine of \$3 against corporation and \$300 against each individual. (F. D. C. No. 35098. Sample Nos. 37495-L, 37497-L, 37500-L.)**

**INFORMATION FILED:** May 28, 1953, District of New Jersey, against Arnold's Pharmacy, Inc., Newark, N. J., Richard Leipert, treasurer of the corporation, and Max Rosenthal, pharmacist.

**NATURE OF CHARGE:** On or about October 21 and 28 and November 6, 1952, while a number of *pulvules containing a mixture of Seconal Sodium and Amytal Sodium* were being held for sale at Arnold's Pharmacy, Inc., after shipment in interstate commerce, the defendants caused various quantities of the drug to be dispensed upon requests for refills of a written prescription therefor without obtaining authorization by the prescriber. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

**DISPOSITION:** A motion to dismiss the information and to suppress evidence was filed on behalf of the defendants, and, on November 5, 1953, the court handed down the following opinion in denial of such motion:

HARTSHORNE, *District Judge*: "The defendants, Arnold's Pharmacy, Inc., a corporation, Richard Leipert, its Treasurer and Manager, and Max Rosenthal, its pharmacist, were all indicted for violating the Pure Food, Drug and Cosmetic Act, commonly known as the Pure Food and Drug Act, as amended June 25, 1938, chapter 675, 52 Stat. 1040, Title 21 U. S. C. A. Supp. Section 301, et seq. Specifically, Count 1 of the Information charged defendants with a certain sale of Seconal Sodium and Amytal Sodium, after shipment in interstate commerce, such drugs being dispensable only on physician's prescription, but being sold by the defendants without such prescription or physician's authorization. Counts 2 and 3 are identic with Count 1, save that they allege similar sales on other dates. All defendants moved to dismiss the Information, as confusing, ambiguous, indefinite, and as founded upon evidence illegally obtained. Defendants also moved to suppress and return the evidence as being seized in violation of the corporation's constitutional rights, i. e., as an unreasonable search and seizure under the Fourth Amendment, and as a violation of the immunity clause in the statute itself, *ibid.* Section 373.

#### THE MOTION TO DISMISS

"The statute clearly is intricate. Indeed, the Supreme Court has recently found a certain portion of the statute Section 301 (f), Title 21 U. S. C. A. Food and Drug, Section 331 (f) invalid, as vague and not giving 'fair warning,' in view of its apparent contrariety with Section 704 (Title 21 U. S. C. A. Section 374). *U. S. v. Cardiff*, 344 U. S. 174 (1952). But such sections are not here involved. Moreover, the basis of the *Cardiff* decision as to the statutory provisions there in question is lacking as to the statutory provisions here involved. In *Cardiff* the Court found that the necessity for the Government to obtain from the owner of the premises his voluntary permission to enter was inexplicable, in view of the penalization, in another portion of the statute, of the owner's refusal to grant such permission. But in the case at bar, as will later appear, no such voluntary permission to enter is connected with the statutory provision in question.

"The differing charge in this case is the sale of a 'habit-forming drug to which Section 352 [502] (d) of this Title applies,' contrary to Section 353 [503] (b) (1) (A), in that it was to be dispensed only upon a written prescription of a physician, but in fact was dispensed without any such authorization; that accordingly same was a statutory 'misbranding,' misbrandings being a violation of the Act under Section 331 (k), the penalties for such misbrandings being set forth in Section 333 (a). When read with care, such statutory provisions appear neither vague nor contradictory, the allusion to Section 352 [502] (d) being merely descriptive of the character of the drug, and not constituting a separate offense from that set forth above.

"The motion to dismiss is denied.

#### THE MOTION TO SUPPRESS EVIDENCE

"A series of affidavits as to the facts underlying the Government's obtaining of this evidence were filed by both sides. While contradictory in part, the truth obviously lies in the oral testimony of the Newark Police Officer, Duffy, who was not only present at the time of the sale and the first search, but who, because he had been a former clerk of defendant corporation, refused

to give the Government an affidavit as to the facts he knew, which forced the Government to subpoena him, and take his testimony orally at the time of the argument on the motion. Indeed, the confidence of the defendants in this officer, their former clerk, even after this sale and seizure, is evidenced by the fact that these defendants themselves got the officer to return later to help them complete, themselves, the search of their records, initiated after the sale. Officer Duffy testifies that, though he happened to be in the pharmacy, in uniform, at the time of the sale, and at the very time the samples and prescription records were first made available to the Government's agents, there was no remonstrance whatever on defendants' part to turning over these samples and shipping records. Nor did he hear the Government's agents, as claimed, tell the defendants to 'read the law,' in reply to a claimed remonstrance on defendants' part. It is obvious that this old friend, in a police uniform, embodied the law to the defendants at the time, and that, had they any thought of objecting to turning over the evidence, they would most certainly have appealed to him for aid. Since they did not do so, it is therefore clear that they willingly turned over the samples, the shipping and other records, as the Government's affidavits say, as well as willingly signing certain statements, and permitting certain photographs to be taken.

"Such being the case, it is perfectly clear that there was no violation of the constitutional rights of the defendant corporation, the owner, as claimed, since such search occurred with the full voluntary permission of defendant Leipert, the Manager of the corporate defendant. *Zap v. U. S.*, 328 U. S. 624 (1946). We turn, then, to the question of whether this evidence was 'obtained under this section' of the law, Title 21 U. S. C. A. Food and Drugs Section 373. For, if it was, that section of the statute expressly provides that same 'shall not be used in a criminal prosecution of the person from whom obtained,' this person meaning both the corporate owner and the individual from whom same was obtained.

"Defendant claims that this evidence, at least the shipping records, and the prescription records, were obtained by virtue of these statutory provisions. The Government claims, on the contrary, that they were obtained, not by virtue of the statute, but by virtue of the permission granted by the corporate owner and its authorized agent. The meaning of this section of the statute is thus in question.

"The meaning of an ambiguous statutory provision<sup>1</sup> is best considered first from the standpoint of those who enacted it. Thus we turn to the purpose of the statute. The report of the committee upon the basis of which the 1938 amended act was adopted, 75th Congress, 3d Session, Report 2139, Food, Drug and Cosmetic Act, April 14, 1938, states, in pertinent part " \* \* \* While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions. \* \* \* The measure contains substantially all the features of the old law that have proved valuable in promoting honesty and fair dealing. But it amplifies and strengthens the provisions designed to safeguard the public health and prevent deception \* \* \*. Carriers are required to make, available for copying, records showing interstate shipments of suspected articles so that Federal jurisdiction can be established \* \* \*. Section 703 (373) requires interstate carriers and receivers to permit access to and the copying of all necessary records to show interstate shipment and thus establish Federal jurisdiction. This provision is necessary

<sup>1</sup> § 373. Records of interstate shipment.

For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Administrator, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: Provided, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: Provided further, That carriers shall not be subject to the other provisions of this chapter by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers. June 25, 1938, c. 675, § 703, 52 Stat. 1057; Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 Fed. Reg. 2422, 54 Stat. 1237.

since some warehousemen and trucking concerns and even some railroads have refused to permit the copying of records which were essential to the institution of proceedings to control abuses of consumer health and welfare. The absence of such provision in the present law has been a definite handicap to its enforcement. \* \* \*'

"In short, the purpose of the provision here in question was to close an earlier loophole in the enforcement provisions of the act, which handicapped its enforcement, this handicap being caused by the refusal of certain carriers, if not others, to permit the copying of essential records. In other words, where, as was generally the case, these records were willingly made available to the Government, so that the Act could readily be enforced, the previous law was effective. But, in cases where this access and copying was refused, the section in question would apply to overcome such refusal, and eliminate such 'handicap to its (the Act's) enforcement.'

"The purpose of the statutory provision was thus to cover cases where the Government was refused access and copying of records. Not only is this clear from a consideration of the Congressional purpose, but the language of the section itself expresses such purpose. That is why the section states that carriers and persons receiving drugs 'shall' permit a governmental officer 'to have access to and to copy all records showing the movement in interstate commerce' and the 'holding thereof \* \* \* after such movement.' That is why the section in question further provides that, if the Government officer not only requests such permission, but accompanies it with a written specification of the drug requested, 'it shall be unlawful for any such carrier or person to fail to permit such access to and copying \* \* \*'. In short, if the person holding the drug and the records refuses access and copying, the statute makes it mandatory upon him to accede, and if he fails to accede after being served such a statement in writing, he is subject to a specific penalty. Title 21 U. S. C. A. Food and Drugs Section 331 (e).

"Considered, therefore, in the light of both the purpose of this statutory amendment and of its terms, it is clear that it is not intended to hamper the powers of the Government in protecting the public, but to add to its powers to that end. Thus since, under well settled principles, those who voluntarily turn over their records to the Government cannot object to their use in criminal proceedings, it can hardly be claimed that this statutory amendment was intended to prevent such use under such circumstances. On the other hand, it is clear both from the purpose of the amendment and its terms, that the section was intended to apply where access to the records was refused the Government. In that event, by proceeding under the statutory provision in question, the Government could obtain access to such records despite such refusal. But, if the Government did so proceed, then the 'evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.'

"Not only does the above seem clear on reason, but it has the support of authority. In *U. S. v. Crescent-Kelvan Co.*, (3 Cir. 1948) 164 F. 2d 582, 586, the Court specifically held that interstate shipping records were lawfully taken by the Government agents. Although the opinion in the main discussed a taking of samples under Section 374, that it was also concerned with section 373, in question here, is apparent from its allusion thereto in footnote 4. This upholding of the taking in *Crescent-Kelvan* was based upon the fact that 'permission to make such an inspection was implicitly granted to them by the individual defendants then present, who had the right to bind the "trust,"' the other defendant. Again, the section in question has been held to afford the Government a 'cumulative procedure \* \* \* without restricting other avenues of information.' *U. S. v. 75 Cases, etc.* (4 Cir. 1944) 146 F. 2d 124, 127. In short, both these cases clearly recognize the fact that a lawful taking in such situations as the present may occur not only in cases of refusal, when the specific statutory requirements are met, but also in cases of permission, when general constitutional requirements are met. Indeed, the Pure Food and Drug Act itself apparently refers to this common law method of obtaining evidence as being in addition to that set forth in Section 373, since another section, Title 21 U. S. C. A. Food and Drug, Section 372 (a), authorizes the Government 'to conduct examinations and investigations for the purposes of this chapter' generally.

"Since the evidence here was voluntarily turned over to the Government by its owners, the conditions for the applicability of the statutory provision in

question did not exist, and the statute does not apply. And since the evidence was not obtained unconstitutionally, defendants' motion for the suppression, impounding and return of the evidence, is denied."

On January 15, 1954, the defendants entered pleas of guilty, and on March 5, 1954, the court fined the corporation \$3 and each individual \$300.

**4203. Misbranding of Seconal Sodium capsules and tablets containing a mixture of crystalline potassium penicillin G and sodium citrate. U. S. v. Aaron Coleman (Coleman's Drug Store). Plea of guilty. Sentence of 6 months in jail and fine of \$1,000. (F. D. C. No. 35107. Sample Nos. 37948-L, 37951-L, 37954-L, 50972-L, 50973-L.)**

**INFORMATION FILED:** June 19, 1953, District of New Jersey, against Aaron Coleman, trading as Coleman's Drug Store, Newark, N. J.

**NATURE OF CHARGE:** On or about October 16, 17, and 21, and November 5, 1952, while a number of *Seconal Sodium capsules and tablets containing a mixture of crystalline potassium penicillin G and sodium citrate* were being held for sale at Coleman's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

**DISPOSITION:** October 1, 1953. The defendant having entered a plea of guilty, the court sentenced him to 1 year in jail and fined him \$1,000. On October 14, 1953, the jail sentence against the defendant was reduced from 1 year to 6 months.

**4204. Misbranding of Seconal Sodium capsules. U. S. v. Junior Amos. Plea of guilty. Fine of \$500 or sentence of 60 days in jail. (F. D. C. No. 33767. Sample No. 4232-L.)**

**INFORMATION FILED:** December 18, 1952, District of Columbia, against Junior Amos, Washington, D. C.

**NATURE OF CHARGE:** On or about December 13, 1952, the defendant sold a number of *Seconal Sodium capsules* in violation of Section 503 (b) (1), which requires that such habit-forming drug as Seconal be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

**DISPOSITION:** December 18, 1952. The defendant having entered a plea of guilty, the court sentenced the defendant to pay a fine of \$500 or to serve 60 days in jail.

**4205. Misbranding of tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfamethazine. U. S. v. Reginald Doyle Groves (Groves Pharmacy). Plea of guilty. Defendant fined \$500 and placed on probation for 5 years. (F. D. C. No. 35121. Sample No. 37398-L.)**

**INFORMATION FILED:** June 18, 1953, District of New Jersey, against Reginald Doyle Groves, trading as Groves Pharmacy, Newark, N. J.

**NATURE OF CHARGE:** On or about December 18, 1952, while a number of *tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfamethazine* were being held for sale at Groves Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such act of dispensing was contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed tablets being misbranded while held for sale.